

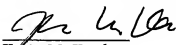
U.S. Patent Application Serial No. 10/723,692
Appeal Brief Under 37 C.F.R. § 41.37
Docket No. 46521-56177

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF ELECTRONIC FILING

I hereby certify that this correspondence has been electronically filed with the
U.S. Patent and Trademark Office via the EFS Web on July 1, 2010.



Kevin M. Kercher
Reg. No. 33,408

In re Application of: James B. McCormick	:	Customer No. 021888
	:	
U.S. Patent Application Serial No. 10/723,692	:	Confirmation No. 8923
	:	
Filed: November 26, 2003	:	Examiner: Jarrett, Lore
	:	
For: HISTOLOGICAL SPECIMEN	:	Group Art Unit: 1797
RETAINING DEVICE	:	
	:	Attorney Docket No. 46521-56177

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Submitted herewith is Applicant's Appeal Brief, appealing the Final Rejection of
Claims 1-7, dated March 1, 2010.

(1) Real Party in Interest

The real party in interest in this Appeal is Leica Biosystems Richmond, Inc. by an assignment recorded on March 26, 2010, at Reel No. 024144, Frame No. 0667.

(2) Related Appeals and Interferences

There are no related appeals or interferences.

(3) Status of Claims

Claims 1-7 are pending in the application. Claims 1-7 have been given a Final Rejection. This is an appeal of the Final Rejection of Claims 1-7. Claims 8-10 were previously cancelled in an amendment dated January 7, 2008.

(4) Status of Amendments

An amendment was filed on June 28, 2010 to rectify a mere typographical error in Claim 1. No new matter was added.

(5) Summary of Claimed Subject Matter

Although Claims 1-7 have been given a Final Rejection, only Claim 1 is an independent claim.

Independent Claim 1

The subject matter of the invention defined by independent Claim 1 is a histological specimen retaining device for processing tissue that is identified by

numeral 10 in FIG. 1. This includes a foldable histological examination liquid permeable sheet 12 having edges (See FIG. 1); a histological examination liquid permeable target 14 disposed on the foldable liquid permeable sheet 12 within the edges (See FIG. 1) of said foldable histological examination liquid sheet 12 and attached with a glue spot (See FIG. 2A), thereby providing extended flap portions 16a-d which flap portions 16a-d are foldable to overlap the histological examination liquid permeable target 14; and a malleable material securing strip 18 attached to the foldable histological examination liquid permeable sheet 12 of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target 14. Applicants' Published Specification, i.e., U.S. Patent Application No. 2005/0112032 in Paragraph [0017], Lines 1-6, Paragraph [0020], Lines 1-13 and Paragraph [0026], Lines 1-10.

(6) Grounds of rejection to be reviewed on Appeal

The grounds of rejection to be reviewed on Appeal is the final rejection of Claims 1, 2 and 6 under 35 U.S.C. § 102(b) for being unpatentable over Pagano (U.S. Patent No. 3,996,006). The grounds of rejection to be reviewed on Appeal also include the final rejection of Claims 3 and 4 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Rochette (U.S. Patent No. 3,537,636). Moreover, the grounds of rejection to be reviewed on Appeal include the final rejection of Claim 5 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Williamson (U.S. Patent No. 5,817,032). Also, the grounds of rejection to be reviewed on Appeal also include the final rejection of

Claim 7 under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Lorincz (U.S. Patent No. 5,812,312). Finally, the grounds of rejection to be reviewed on Appeal also include the final rejection of Claims 1, 2 and 6 under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. (U.S. Patent No. 5,932,430) in view of Pagano (U.S. Patent No. 3,996,006).

(7) Argument

Claim Rejections – 35 U.S.C. § 102(b)

Claims 1, 2 and 6 were rejected under 35 U.S.C. § 102(b) for being unpatentable over Pagano (U.S. Patent No. 3,996,006).

Independent Claim 1

Claim 1 recites: “...A histological specimen retaining device for processing tissue, said device comprising: a foldable histological examination **liquid permeable sheet** having edges; a **histological examination liquid permeable target** disposed on the foldable **liquid permeable sheet within the edges** of said foldable histological examination liquid permeable sheet and attached with a glue spot, thereby providing extended flap portions which flap portions are foldable to **overlap the histological examination liquid permeable target**; and a **malleable material securing strip** attached to the foldable histological examination liquid permeable sheet of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target.” (emphasis added).

Pagano recites in Column 2, Lines 24-40: "To use the slide device, the patient separates cover 8 from panel 4 at the spot 52, **opens the cover** and applies with an applicator a thin smear of a specimen from one portion of his stool on paper 26 through opening 22. He then applies from another portion of his stool a thin smear on paper 26 through opening 24. **He then closes the cover locking tab 14 in openings 16 and 18** and returns the slide to his physician. On receiving the slide, the physician pulls tabs 38 and 40 free of rear panel 6 and opens them outwardly. **Through the opening thus made the physician applies a peroxide solution on the guaiac impregnated paper 26 opposite each of the openings 22 and 24 and observes the test results, i.e., in the occult blood test the degree to which the color blue is developed.** This provides a good side-by-side comparison of test results from two different portions of the patient's stool." (emphasis added). Therefore, Pagano discloses a stool-sampling device. Pagano does not disclose a "foldable histological examination liquid permeable sheet" but an impermeable cardboard device with flaps that open to allow the physician to apply a peroxide solution. Therefore, in order to receive the peroxide solution, the closure flap needs to be open. If the foldable sheet is permeable, the closure flap would not provide any function. Therefore, a person of ordinary skill in the art would assume that the closure flap is liquid impermeable by a reading of Pagano.

Therefore, the absorbent paper 26 found in Pagano could be contaminated if the closure flap was permeable and it was irrelevant as to whether or not the closure flap was open. Therefore, not only does Pagano not disclose this feature, but it would destroy the Applicant's Invention, as claimed, for its stated purpose of providing a foldable liquid permeable sheet having extended flap portions which flap portions are

foldable to overlap the liquid permeable target, where the liquid is histological examination liquid. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Moreover, when evaluating a claim for anticipation, all claim limitations must be considered. *In re Evanega*, 829 F.2d 1110, 4 U.S.P.Q.2d 1249 (Fed. Cir. 1987).

Therefore, since the foldable sheet must be open to receive the peroxide solution, this clearly indicates that the cardboard foldable sheet in Pagano is liquid impermeable. There would be no need to open the flap in Pagano if the cardboard was already liquid permeable so that the peroxide solution could already pass directly into the target.

Also, Pagano discloses in Column 1, Lines 64-68: "Front panel 4 has a pair of adjacent openings 22 and 24. A sheet of absorbent paper 26, for example, filter paper overlies (as viewed in FIG. 1) openings 22 and 24. Sheet 26 is **impregnated with a reagent such as guaiac.**" (emphasis added). If the flap was liquid permeable, the absorbent paper impregnated with a reagent could be ruined by liquid passing through the flap into the absorbent paper. The reason for the flap in Pagano is so that the absorbent paper is only exposed to fecal matter when acquiring a stool specimen and then open to receive peroxide solution during testing to develop the reagent. Liquid passing onto the absorbent paper would literally destroy the absorbent paper for its

desired purpose by diluting and removing both the stool specimen and the reagent. A reagent is defined as "a substance that, because of the reactions it causes, is used in analysis and synthesis." See "reagent." *Dictionary.com Unabridged*. Random House, Inc. 30 Jun. 2010. <Dictionary.com <http://dictionary.reference.com/browse/reagent>>, which is attached in Appendix A.

Moreover, proper application of a reference against a device described and claimed in a patent application requires broadly that the anticipatory device be substantially the same as the anticipated device in function, structure and result. In this case, the function of opening a flap to obtain stool sample on an absorbent paper, opening the flap again to apply a peroxide solution to the absorbent paper having a diagnostic reagent is very different than a foldable liquid permeable sheet having edges with a liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said sheet, thereby providing extended flap portions which flap portions are foldable to overlap the liquid permeable target, where the liquid is a histological examination liquid. Accordingly, the structure is very different. Finally, the results are markedly different with Pagano for collecting stool samples and applying a peroxide solution to an absorbent paper having a reagent with a protective cover that is only open for obtaining a sample and testing versus the Applicant's Invention that is for processing tissue for histological examination.

Moreover, cardboard and paper are not inherently liquid permeable and many papers and cardboards are liquid impermeable. The common disposable coffee cup is merely one example. It is respectfully believed for something to be inherent from a disclosure; it must, by necessity, flow from that disclosure. Due to the numerous

examples of liquid impermeable cardboard and liquid impermeable paper present in the world, it is very clear that liquid permeability is not an aspect that flows from the word "cardboard" or "paper." Moreover, the cardboard flaps disclosed in Pagano would be rendered superfluous if these flaps were liquid permeable. The flaps in Pagano protect the absorbent paper from being contaminated so that only the specimen and peroxide solution can be selectively applied and there is protection from liquid contamination. Therefore, the inherent aspect of the cardboard or paper in Pagano would be that someone with ordinary skill in the art would clearly understand that the cardboard or paper in Pagano is liquid impermeable rather than liquid permeable. This is the inherent aspect of Pagano that would flow from Pagano.

In addition, Pagano does not disclose a malleable securing strip but rather a slit. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to target 14; thereby, securing the extended flap portions 16a-d in the folded condition.** Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added) (Paragraph [0026], Lines 1-10). Also: "Malleable securing strip 18 can be **any material that is formable or malleable**, but it is **preferred that strip 18 is either a metal wire or a strip of heavy metal foil.** The wire or foil needs to have **appropriate dimensions to allow for a one time use-easy closure and clamping**, as well as, positive release of

extended flap portions 16a-d (described in more detail below)." (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast, the area marked by numeral 52 is described as "Cover 8 is now hinged about crease 12 and secured to panel 4 **by a spot of glue 52.**" (Pagano, Column 2, Lines 22-23) (emphasis added). The area where numeral 52 is located is identified by the Examiner as corresponding to the malleable securing strip. It is respectfully believed that a slit, which is an opening or void, is a very different item than a malleable securing strip. "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). It is respectfully believed that a slit is not identical to a malleable securing strip. An opening or void cannot function in the same manner as a solid object, i.e., malleable securing strip. Also, a piece of hard glue cannot be construed as malleable. If the piece of hard glue is not considered the malleable material securing strip, then the remainder of the area at the location is merely part of the blank 2. Therefore, this feature is wholly absent from Pagano. For a valid rejection under 35 U.S.C. §102, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

Moreover, Claim 1 requires that the histological examination liquid permeable target be attached to the foldable histological examination liquid permeable sheet with a spot of glue. In marked contrast the glue in Pagano is to "...form the completed slide 50 shown in FIG. 2, blank 2 is folded along crease line 10 to bring panels 4 and 6 together and hold them together principally by the glue at 35. Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52." (Pagano, Column 2, Lines

19-23). It is to fold the panels of the blank together and not secure a histological examination liquid permeable target to a foldable histological examination liquid permeable sheet. Under 35 U.S.C. §102, “the identical invention must be shown in as complete detail as is contained in the...claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Moreover, Applicant’s recited invention of Claim 1 is directed to “processing tissue samples in preparation for histological examination.” Tissue is defined as: “An aggregation of morphologically similar cells and associated intercellular matter acting together to perform one or more specific functions in the body. **There are four basic types of tissue: muscle, nerve, epidermal, and connective.**” (emphasis added). tissue. Dictionary.com. *The American Heritage® Dictionary of the English Language*, Fourth Edition. Houghton Mifflin Company, 2004. <http://dictionary.reference.com/browse/tissue> (accessed: June 30, 2010), see Appendix B.

In marked contrast, a stool is defined as “fecal matter from a single bowel movement.” stool. Dictionary.com. *The American Heritage® Dictionary of the English Language*, Fourth Edition. Houghton Mifflin Company, 2004, <http://dictionary.reference.com/browse/stool>, see Appendix C. “Fecal matter” is solid excretory product evacuated from the bowels. *fecal matter*. Dictionary.com. WordNet® 3.0. Princeton University. http://dictionary.reference.com/browse/fecal_matter (accessed: June 30, 2010), see Appendix D. Therefore, stool is human waste product and not tissue, i.e., muscle tissue, nerve tissue, epidermal tissue, and connective tissue, found in the human body.

In addition, histology is the anatomical study of the **microscopic structure** of **animal** and plant **tissues**. (emphasis added) histology. Dictionary.com. The *American Heritage® Dictionary of the English Language*, Fourth Edition. Houghton Mifflin Company, 2004. <http://dictionary.reference.com/browse/histology> (accessed: June 30, 2010), see Appendix E. The stool sample testing of Pagano only involves interactions with the stool and reagents to obtain a blue color. There is not the slightest hint or suggestion regarding microscopic examination. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Moreover, when evaluating a claim for anticipation, all claim limitations must be considered. *In re Evanega*, 829 F.2d 1110, 4 U.S.P.Q.2d 1249 (Fed. Cir. 1987). In this case, histological examination of tissue is not found in Pagano and it is respectfully believed that this feature must be present for a valid rejection under 35 U.S.C. §102(b).

Therefore, it is respectfully believed that the rejection of Claim 1 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Dependent Claim 2

Claim 2 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 2 recites: "wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet to allow for **closure and clamping of the folded flap portions as well as positive release of the folded flap portions.**" (emphasis added). In marked contrast in Pagano, the area identified by numeral 52 as being the malleable material securing strip is either a piece of hard glue that is not located at the edge or just a portion of the blank 2. Therefore, there is nothing that comports with a malleable material securing strip. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Therefore, it is respectfully believed that the rejection of Claim 2 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Dependent Claim 6

Claim 6 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 102(b) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not anticipated, then any claim depending therefrom is also not anticipated. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 6 recites: "wherein the histological examination liquid permeable target is a liquid permeable **paper sheet** having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet." (emphasis added). Moreover, Claim

6 requires that the histological examination liquid permeable target be attached to the foldable histological examination liquid permeable sheet with a spot of glue. In marked contrast, the glue in Pagano is to "...form the completed slide 50 shown in FIG. 2, blank 2 is folded along crease line 10 to bring panels 4 and 6 together and hold them together principally by the glue at 35. Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52." (Pagano, Column 2, Lines 19-23). It is to fold the panels of the blank together and not secure a histological examination liquid permeable target to a foldable histological examination liquid permeable sheet. Under 35 U.S.C. §102, "the identical invention must be shown in as complete detail as is contained in the...claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

Therefore, it is respectfully believed that the rejection of Claim 6 under 35 U.S.C. § 102(b) as being unpatentable over Pagano should be reversed.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 3 and 4 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Rochette (U.S. Patent No. 3,537,636).

Dependent Claim 3

Claim 3 depends from dependent Claim 2 and independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious,

then any claim depending therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 3 requires that the malleable securing strip is a **metal wire**. This does not mean the malleable securing strip includes or comprises a metal wire **but the malleable securing strip is a metal wire**.

Pagano does not disclose a malleable securing strip but rather a slit. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to target 14; thereby, securing the extended flap portions 16a-d in the folded condition**. Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added) (Paragraph [0026], Lines 1-10). Also: "Malleable securing strip 18 can be **any material that is formable or malleable**, but it is **preferred that strip 18 is either a metal wire or a strip of heavy metal foil**. The wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping, as well as, positive release of **extended flap portions 16a-d** (described in more detail below)." (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast in Pagano, the area marked by numeral 52 is described as "Cover 8 is now hinged about crease 12 and secured to panel 4 **by a spot of glue 52**." (Pagano, Column 2, Lines 22-23) (emphasis added). The

area where numeral 52 is located is identified by the Examiner as corresponding to the malleable securing strip. It is respectfully believed that a slit, which is an opening or void, is a very different item than a malleable securing strip. An opening or void cannot function in the same manner as a solid object, i.e., malleable securing strip. Also, a piece of hard glue cannot be construed as malleable. If the piece of hard glue is not considered the malleable material securing strip, then the remainder of the area at the location is merely part of the blank 2. Therefore, this feature is wholly absent from Pagano. Consequently, there is no need to add a piece of metal wire found in Rochette and add this feature to Pagano. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, **with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference;** (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately." (emphasis added). Federal Register / Volume 72, No. 195 /

Wednesday, October 10, 2007 / Notices, Page 57529, "*Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc.*" It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a metal wire would not operate like a slit. A person of ordinary skill in the art would not make a substitution of the wire disclosed in Rochette for the slit disclosed in Pagano if this substitution would destroy the function and purpose of the stool sampling device disclosed in Pagano. In this case, a person of ordinary skill in the art would not want a metal wire on the edge of the blank 2 since a person of ordinary skill in the art would find that metal wire creates additional issues. If the blank 2 in Pagano had a metal wire at the edge, it could make the folding of the blank 2 more difficult since it would bend and could have a harder time being placed into the slit 16.

Therefore, it is respectfully believed that the rejection of Claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Rochette should be reversed.

Dependent Claim 4

Claim 4 depends from dependent Claim 2 and independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 4 requires that the malleable securing strip is a **metal foil**. This does not mean the malleable securing strip includes or comprises a metal wire **but the malleable securing strip is a metal foil**.

Pagano does not disclose a malleable securing strip but rather a slit. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to target 14; thereby, securing the extended flap portions 16a-d in the folded condition**. Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added) (Paragraph [0026], Lines 1-10). Also: "Malleable securing strip 18 can be **any material that is formable or malleable**, but it is **preferred that strip 18 is either a metal wire or a strip of heavy metal foil**. The wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping, as well as, positive release of **extended flap portions 16a-d** (described in more detail below)." (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast in Pagano, the area marked by numeral 52 is described as "Cover 8 is now hinged about crease 12 and secured to panel 4 **by a spot of glue 52**." (Pagano, Column 2, Lines 22-23) (emphasis added). The area where numeral 52 is located is identified by the Examiner as corresponding to the malleable securing strip. It is respectfully believed that a slit, which is an opening or

void, is a very different item than a malleable securing strip. An opening or void cannot function in the same manner as a solid object, i.e., malleable securing strip. Also, a piece of hard glue cannot be construed as malleable. If the piece of hard glue is not considered the malleable material securing strip, then the remainder of the area at the location is merely part of the blank 2. Therefore, this feature is wholly absent from Pagano. Consequently, there is no need to add a piece of metal foil found in Rochette and add this feature to Pagano. If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). Moreover, "all words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (C.C.P.A. 1970).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, **with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it **did separately**." (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, *"Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court*

Decision in KSR International Co. v. Teleflex Inc." It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since a metal foil would not operate like a slit. A person of ordinary skill in the art would not make a substitution of the foil disclosed in Rochette for the slit disclosed in Pagano if this substitution would destroy the function and purpose of the stool sampling device disclosed in Pagano. In this case, a person of ordinary skill in the art would not want a metal foil on the edge of the blank 2 since a person of ordinary skill in the art would find that metal foil would create additional issues. If the blank 2 in Pagano had a metal foil at the edge, it could make the folding of the blank 2 more difficult since it would bend and could have a harder time being placed into the slit 16.

Therefore, it is respectfully believed that the rejection of Claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Rochette should be reversed.

Claim 5 was rejected under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Williamson (U.S. Patent No. 5,817,032).

Dependent Claim 5

Claim 5 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending

therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

The target in Pagano is a stool sample. The addition of a reagent to the stool sample makes sense because there is a chemical reaction with the stool sample to determine the presence of occult blood. Therefore, the complete access to the stool sample is required so that a chemical reaction can take place. In marked contrast, the Examiner is alleging on Page 4, Lines 11-21 of the September 3, 2009 Office Action that: "Williamson discloses in his abstract placing a **tissue biopsy sample on a tissue trapping and supporting material** that can withstand tissue preparation procedures and which can be cut with a microtome. Williamson further discloses spraying a **thin layer of agar or other gel over the tissue** and filter (i.e., col. 16, lines 43-59). At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify Pagano's liquid permeable target by adding a **binder, such as agar, to the tissue sample** because adding agar to tissue samples is well known as "cell block preparation," which is a technique that allows the user to easily prepare the sample for analysis (i.e., Williamson, Column 1, Lines 32-37)." (emphasis added). Therefore, adding a binder and using a tissue trapping material would operate to destroy the invention disclosed in Pagano and prevent an even and consistent chemical reaction between the stool sample and the reagent from taking place. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959).

"To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art being the lack of actual combination of the elements in a single prior art reference; (2) **a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, each element merely would have performed the same function as it did separately.**" (emphasis added). Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, *"Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc."* It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office since adding a binder or gel would most likely operate to prevent or inhibit a reaction between a stool sample and reagent from taking place. It would not be the same function as performed separately and no one with ordinary skill in the art would add material that would prevent or inhibit the reaction between the stool sample and the reagent from taking place since that is the purpose and function of Pagano.

Therefore, it is respectfully believed that the rejection of Claim 5 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Williamson should be reversed.

Claim 7 was rejected under 35 U.S.C. § 103(a) for being unpatentable over Pagano (U.S. Patent No. 3,996,006) in view of Lorincz (U.S. Patent No. 5,812,312).

Dependent Claim 7

Claim 7 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

Claim 7 recites: "...an X and Y coordinate marking lines centered on the histological examination liquid permeable target." Lorincz discloses a: "...reference standards, such as a sizing grid 19 or the like, can also be incorporated as by etching or photographic reproduction onto the surface of the slide or film to allow sizing and quantitation of cells, microorganisms or the like." (Lorincz, Column 4, Lines 44-48). This grid 19 is not a "centered X and Y axis." There is no semblance of **centered X** and Y axis disclosed in Pagano. It is respectfully believed to be axiomatic that a feature not disclosed in two cited references cannot come into being by their combination.

Moreover, this grid 19 in Lorincz appears on a liquid impermeable microscope slide 11 or film 16. There is no reason to use a grid on a liquid impermeable surface and transfer that to a histological examination liquid permeable target enclosed by the foldable histological examination liquid permeable sheet. The grid is required for viewing under a microscope and cannot be enclosed by foldable histological examination liquid permeable sheet. "If proposed modification would render the prior

art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972).

Therefore, Lorincz clearly teaches away from the Applicant's Invention, as claimed, in addition to destroying the Applicant's Invention for its intended purpose. The Supreme Court held in *U.S. v. Adams*, 383 U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art or by experts in the art at (and/or after) the time the invention was made. This is specifically mandated by the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.02, which recites: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention". *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, "...if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the

desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990). Moreover, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959).

In addition, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007). In determining obviousness, the proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference**; (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the same function as it did separately**" (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, "Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*"). It is

respectfully believed that it is very clear that this rejection completely fails the new *KSR* Guidelines promulgated by the United States Patent Office.

Therefore, it is respectfully believed that the rejection of Claim 7 under 35 U.S.C. § 103(a) as being unpatentable over Pagano in view of Lorincz should be reversed.

Claims 1, 2 and 6 were rejected under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. (U.S. Patent No. 5,932,430) in view of Pagano (U.S. Patent No. 3,996,006).

Independent Claim 1

Claim 1 recites: "A histological specimen retaining device for processing tissue, said device comprising: a foldable histological examination liquid permeable sheet having edges; a histological examination liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said foldable histological examination liquid permeable sheet and attached with a glue spot, thereby providing extended flap portions which flap portions are foldable to overlap the histological examination liquid permeable target; and a malleable material securing strip attached to the foldable histological examination liquid permeable sheet of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target." (emphasis added).

Pagano recites in Column 2, Lines 24-40: "To use the slide device, the patient separates cover 8 from panel 4 at the spot 52, **opens the cover** and applies with an

applicator a thin smear of a specimen from one portion of his stool on paper 26 through opening 22. He then applies from another portion of his stool a thin smear on paper 26 through opening 24. **He then closes the cover locking tab 14 in openings 16 and 18 and returns the slide to his physician. On receiving the slide, the physician pulls tabs 38 and 40 free of rear panel 6 and opens them outwardly. Through the opening thus made the physician applies a peroxide solution on the guaiac impregnated paper 26 opposite each of the openings 22 and 24 and observes the test results, i.e., in the occult blood test the degree to which the color blue is developed.** This provides a good side-by-side comparison of test results from two different portions of the patient's stool." (emphasis added). Therefore, Pagano discloses a stool-sampling device. Pagano does not disclose a "foldable histological examination liquid permeable sheet" but an impermeable cardboard device with flaps that open to allow the physician to apply a peroxide solution. Therefore, in order to receive the peroxide solution, the closure flap needs to be open. If the foldable sheet is permeable, the closure flap would not provide any function. Therefore, a person of ordinary skill in the art would assume that the closure flap is liquid impermeable by a reading of Pagano.

Therefore, the absorbent paper 26 found in Pagano could be contaminated if the closure flap was permeable and it was irrelevant as to whether or not the closure flap was open. Therefore, not only does Pagano not only does not disclose this feature but it would destroy the Applicant's Invention, as claimed, for its stated purpose of providing a foldable liquid permeable sheet having extended flap portions which flap portions are foldable to overlap the liquid permeable target, where the liquid is histological examination liquid.

Moreover, Larka et al. recites: "At the lab, the technician accesses the filter paper 20 through the flap 22 and removes the portions 24 of the paper bounded by the score lines 26 and immerses them in diluent solution such as BSA/PBS to prepare a sample solution which can be used in the assay as previously illustrated in Example 4." (Larka et al., Column 8, Lines 10-15). This paper card 10 clearly appears to be impermeable to fluids and not permeable since there would be no need to open the flap if the paper card 10 was permeable. It is respectfully believed that the combination of two impermeable stool sampling devices, i.e., Pagano and Larka et al., does not create a "histological examination liquid permeable sheet" by their combination.

Moreover, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972).

Therefore, the combination of Larka et al. and Pagano clearly teaches away from the Applicant's Invention, as claimed, in addition to destroying the Applicant's Invention for its intended purpose. The Supreme Court held in *U.S. v. Adams*, 383 U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art or by experts in the art at

(and/or after) the time the invention was made. This is specifically mandated by the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.02, which recites: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention". *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Consequently, permeability of both the histological examination liquid permeable target and the foldable histological examination liquid permeable sheet is crucial to Applicant's Invention, as claimed. Therefore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Moreover, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007). In determining obviousness, the proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that

the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference;** (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the same function as it did separately**" (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, *"Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc."*). It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office.

Therefore, it is respectfully believed that the rejection of Claim 1 under 35 U.S.C. § 103(a) for being unpatentable over Larka et al. in view of Pagano should be reversed.

Dependent Claim 2

Claim 2 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Larka et al. in view of Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 2 recites: "wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet **to allow for**

closure and clamping of the folded flap portions as well as positive release of the **folded flap portions.**" (emphasis added). In marked contrast in Pagano, the area identified by numeral 52 as being the malleable material securing strip is either a piece of hard glue that is not located at the edge or just a portion of the blank 2. Pagano does not disclose a malleable securing strip but rather a slit. For example, Applicant's Published Patent Application, i.e., U.S. Published Patent Application No. 20050112032, recites: "Again referring to FIG. 1, histological retaining device comprises a malleable securing strip 18. When extended flap portions 16a-d are folded to overlap target 14 (described in more detail below), **malleable securing strip 18 is designed to hold, crimp, or clamp the folded extended flap portions 16a-d to target 14; thereby, securing the extended flap portions 16a-d in the folded condition.** Additionally, malleable securing strip 18 provides positive release upon the opening of folded flap portions 16a-d after processing of the sample." (emphasis added) (Paragraph [0026], Lines 1-10). Also: "Malleable securing strip 18 can be **any material that is formable or malleable, but it is preferred that strip 18 is either a metal wire or a strip of heavy metal foil. The wire or foil needs to have appropriate dimensions to allow for a one time use-easy closure and clamping, as well as, positive release of extended flap portions 16a-d** (described in more detail below)." (emphasis added) (Paragraph [0028], Lines 1-7). In marked contrast in Pagano, the area marked by numeral 52 is described as "Cover 8 is now hinged about crease 12 and secured to panel 4 **by a spot of glue 52.**" (Pagano, Column 2, Lines 22-23) (emphasis added). The area where numeral 52 is located is identified by the Examiner as corresponding to the

malleable securing strip. It is respectfully believed that a slit, which is an opening or void, is a very different item than a malleable securing strip. An opening or void cannot function in the same manner as a solid object, i.e., malleable securing strip. Also, a piece of hard glue cannot be construed as malleable. If the piece of hard glue is not considered the malleable material securing strip, then the remainder of the area at the location is merely part of the blank 2. Therefore, this feature is wholly absent from Pagano.

In addition, the Examiner on Page 7, Lines 7-10 of the Final Rejection, dated March 1, 2010 states that Larka et al. does not disclose a malleable securing strip. It is respectfully believed that a feature that is not disclosed in either of two cited references cannot come into being by their combination. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is **not sufficient** to establish a prima facie case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 U.S.P.Q.2d 1300 (Bd. Pat. App. & Inter. 1993). **"[R]ejections on obviousness cannot be sustained by mere conclusory statements;** instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (emphasis added) *In re Kahn*, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006). Manual for Examining Procedure (M.P.E.P. §2143.01 IV).

Therefore, it is respectfully believed that the rejection of Claim 2 under 35 U.S.C. § 102(b) as being unpatentable over Larka et al. in view of Pagano should be reversed.

Dependent Claim 6

Claim 6 depends from independent Claim 1, which is respectfully believed to overcome the 35 U.S.C. § 103(a) rejection over Larka et al. in view of Pagano in the same manner as Claim 1 as described above. If an independent claim is not obvious, then any claim depending therefrom is also not obvious. *In re Fine*, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988).

In addition, Claim 6 recites: “wherein the histological examination liquid permeable target is a liquid permeable **paper sheet** having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet.” (emphasis added). Moreover, Claim 6 requires that the histological examination liquid permeable target be attached to the foldable histological examination liquid permeable sheet with a spot of glue. In marked contrast, the glue in Pagano is to “...form the completed slide 50 shown in FIG. 2, blank 2 is folded along crease line 10 to bring panels 4 and 6 together and hold them together principally by the glue at 35. Cover 8 is now hinged about crease 12 and secured to panel 4 by a spot of glue 52.” (Pagano, Column 2, Lines 19-23). It is to fold the panels of the blank together and not secure a histological examination liquid permeable target to a foldable histological examination liquid permeable sheet.

Moreover, Larka et al. recites: "At the lab, the technician accesses the filter paper 20 through the flap 22 and removes the portions 24 of the paper bounded by the score lines 26 and immerses them in diluent solution such as BSA/PBS to prepare a sample solution which can be used in the assay as previously illustrated in Example 4." (Larka et al., Column 8, Lines 10-15). This paper card 10 clearly appears to be impermeable to fluids and not permeable since there would be no need to open the flap if the paper card 10 was permeable. It is respectfully believed that the combination of two impermeable stool sampling devices, i.e., Pagano and Larka et al., does not create a "histological examination liquid permeable sheet" by their combination.

Moreover, "if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). "In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 U.S.P.Q. 560, 562 (C.C.P.A. 1972).

Therefore, the combination of Larka et al. and Pagano clearly teaches away from the Applicant's Invention, as claimed, in addition to destroying the Applicant's Invention for its intended purpose. The Supreme Court held in *U.S. v. Adams*, 383 U.S. 39, 148 U.S.P.Q. 479 (1966), that one important indicium of nonobviousness is "teaching away" from the claimed invention by the prior art or by experts in the art at

(and/or after) the time the invention was made. This is specifically mandated by the Manual of Patent Examining Procedure (M.P.E.P.) § 2141.02, which recites: "A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention". *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984). Moreover, "...if proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d 1430 (Fed. Cir. 1990).

Consequently, permeability of both the histological examination liquid permeable target and the foldable histological examination liquid permeable sheet is crucial to Applicant's Invention, as claimed. Therefore, if the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 U.S.P.Q. 349 (C.C.P.A. 1959). Moreover, there is no teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention. *KSR International Co. v. Teleflex Inc.*, 82 U.S.P.Q.2d 1385 (U.S. 2007). In determining obviousness, the proper analysis is whether the claimed invention would have been

obvious to one of ordinary skill in the art after consideration of all the facts. "To reject a claim based on this rationale, U.S. Patent Office personnel must resolve the Graham factual inquiries. Office personnel must then articulate the following: (1) a finding that the prior art included each element claimed, although not necessarily in a single prior art reference, with the only difference between the claimed invention and the prior art **being the lack of actual combination of the elements in a single prior art reference;** (2) a finding that one of ordinary skill in the art could have combined the elements as claimed by known methods, and that in combination, **each element merely would have performed the same function as it did separately**" (emphasis added) (Federal Register / Volume 72, No. 195 / Wednesday, October 10, 2007 / Notices, Page 57529, *"Examination Guidelines for Determining Obviousness Under 35 U.S.C. § 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc."*). It is respectfully believed that it is very clear that this rejection completely fails the new KSR Guidelines promulgated by the United States Patent Office.

Therefore, it is respectfully believed that the rejection of Claim 6 under 35 U.S.C. § 103(a) as being unpatentable over Larka in view of Pagano should be reversed.

For all the reasons set forth above, it is respectfully submitted that the rejections of Claims 1-7 should be reversed and the Claims allowed.

(8) Claims Appendix

1. A histological specimen retaining device for processing tissue, said device comprising: a foldable histological examination liquid permeable sheet having edges, a histological examination liquid permeable target disposed on the foldable liquid permeable sheet within the edges of said foldable histological examination liquid permeable sheet and attached with a glue spot, thereby providing extended flap portions which flap portions are foldable to overlap the histological examination liquid permeable target; and a malleable material securing strip attached to the foldable histological examination liquid permeable sheet of a length sufficient to secure said folded flap portions overlapping said histological examination liquid permeable target.

2. The histological specimen retaining device of claim 1 further comprising wherein the malleable material securing strip is attached at an edge of the histological examination liquid permeable sheet to allow for closure and clamping of the folded flap portions as well as positive release of the folded flap portions.

3. The histological specimen retaining device of claim 2, wherein the malleable material securing strip is a metal wire.

4. The histological specimen retaining device of claim 2, wherein the malleable material securing strip is metal foil.

5. The histological specimen retaining device of claim 1, further comprising wherein the histological examination liquid permeable target is coated with a release agent.

6. The histological specimen retaining device of claim 1, wherein the histological examination liquid permeable target is a liquid permeable paper sheet having a glue spot located thereon for attaching the histological examination liquid permeable target to the foldable histological examination liquid permeable sheet.

7. The histological specimen retaining device of claim 1, further comprising an X and Y coordinate marking lines centered on the histological examination liquid permeable target.

(9) Evidence Appendix

Appendix A:

re·a·gent

ri'erdʒəntShow Spelled[ree-ey-juh nt]

—**noun** *Chemistry* .

a substance that, because of the reactions it causes, is used in analysis and synthesis.

Dictionary.com Unabridged

Based on the Random House Dictionary, © Random House, Inc. 2010.

Appendix B:

tis·sue ⓘ(tĭsh'ōō) ⓘ
n.

Biology An aggregation of morphologically similar cells and associated intercellular matter acting together to perform one or more specific functions in the body. There are four basic types of tissue: muscle, nerve, epidermal, and connective.

The American Heritage® Dictionary of the English Language, Fourth Edition
Copyright © 2009 by Houghton Mifflin Company.
Published by Houghton Mifflin Company. All rights reserved.

Appendix C:

stool ⓘ(stōōl) ⓘ
n.

Fecal matter from a single bowel movement.

The American Heritage® Dictionary of the English Language, Fourth Edition
Copyright © 2009 by Houghton Mifflin Company.
Published by Houghton Mifflin Company. All rights reserved.

Appendix D:



fecal matter

noun

solid excretory product evacuated from the bowels

WordNet® 3.0, © 2006 by Princeton University.

Appendix E:

his·tol·o·gy  (hĭ-stŏl'ə-jē) 

n. *pl.* his·tol·o·gies

The anatomical study of the microscopic structure of animal and plant tissues.
The American Heritage® Dictionary of the English Language, Fourth Edition
Copyright © 2009 by Houghton Mifflin Company.
Published by Houghton Mifflin Company. All rights reserved.

(10) Related Proceedings Appendix

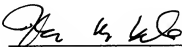
None.

It is respectfully submitted that, for the reasons set forth above, the rejections of Claims 1-7 were made in error and should be reversed and the Claims 1-7 allowed.

An oral hearing is not requested.

Respectfully submitted,

Thompson Coburn LLP

By: 
Kevin M. Kercher
Reg. No. 33,408
One US Bank Plaza
St. Louis, MO 63101-1693
(314) 552-6000
(314) 552-7000 (fax)
Date: July 1, 2010